REMARKS

Claims 1-14 are pending in the application.

The Examiner has rejected all of the claims as being anticipated over the disclosure of United States Patent No. 5,824,096 of Pappas and/or rendered obvious by the disclosure of Pappas either considered alone or in combination with one of:

(a) United States Patent Application No. 2003/0171825 to Blunn ("Blunn");

(b) Marshall *et al.* Cementless Titanium Tapered-Wedge Femoral Stem ("Marshall"); and

(c) WO 99/64491 to Spaans ("Spaans").

The Examiner's Interpretation of Pappas:

The Examiner characterizes the primary reference Pappas as teaching a hinge knee replacement device that is implanted into the femur and tibia having a hinge assembly which includes a circular cylindrical shaft that is pressed fit into a frustoconical bushing that is so dimensioned such that it can displace axially in the tapered cavity of the tibial body. The Examiner equates the circular cylindrical shaft of Pappas to the adaptation tube of the invention. Additionally, the Examiner concludes, without providing support for such conclusion, that since the bushing is placed into a tapered cavity, it necessarily widens from the extra corporal direction to the intra corporal direction as shown in Figure 14 (of Pappas). The Examiner states that the bushing surface articulates with the polished inner tapered cavity of the tibial body; on this basis the Examiner asserts that the articulation with the cavity of the tibial body "would necessarily" require that the busing surface is smooth.

Claims 1, 6, and 14: The Examiner contends that claim 1, 6, and 14 are anticipated under § 102(b) by Pappas, based on her reading of Pappas, as described above. The applicants traverse the rejection.

As stated in the prior response, Pappas does not anticipate the invention as it does not teach all elements of the invention either expressly or inherently. Pappas teaches a conventional common clamping seat positioned within the knee implant (e.g., Fig, 14). The Pappas "bushing" 340 (seen in Fig, 8) is not a counterpart element to the "bush" element (5) of the invention. As is clear from the Pappas Fig. 1, the bushing 340 is located within the "tibial component" 500 (not the leg tissue) and makes no contact with the surrounding tissues.

In addition, the Examiner argues that the since the bushing 340 is placed into a cavity 503 (referred to by the Examiner as a "tapered cavity"), it "necessarily" (inherently) widens from the extracorporal direction to the intracorporal direction. Logic dictates however, that there is no "necessary" correspondence of the geometry of an inner structure (like the bushing) to it's outer covering or shell. The fact that a certain result or characteristic may occur or may be present in the prior art is not sufficient to establish the inherency that result for characteristic. *In re Rijckaert*, 9 F.3d 1513, 1534 (reversed rejection because inherency was based on what would result due to optimization of conditions not what was necessarily present in the prior art). The mere fact that a certain thing may result from a given set of circumstances is not sufficient'". *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (The claims were drawn to a disposal diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and how that the reference did not disclose a separate third fastening element, either expressly or inherently.". The Examiner has provided no cogent technical reason for her assertion that the shaped of the bushing 340 must resemble the geometry of the cavity 503. The burden to establish inherency has not been met.

In stark contrast, the bush (5) of the invention is specifically structurally adapted and orientated with the implant to co-act with the tissues of the human body and leverage results of such interaction to form a seal that increases in effectiveness the longer the implant is worn. The applicant writes:

> This object is achieved in the following manner: the bush widens out significantly from the extracorporally oriented side to the intracorporally oriented side and comprises a smooth surface. The soft tissues surrounding the spacer, specifically the bush, atrophy onto the bush, and significantly more so in the area of the bush facing the intracorporal direction than in the part facing the extracorporal direction, due to the special design of the bush. This adds up to a constantly increasing seal from the part of the bush facing in the extracorporal direction to the part facing in the intracorporal direction. This can also be expected from surrounding fatty tissue, so that adipose patients can also be optimally cared for.

Paragraph [0006]. Pappas lacks at least a disclosure of a bush (5) element as such term is used with the claims, wherein the bush widens out significantly from the end thereof facing the extracorporal direction to the end thereof facing the intracorporal direction.

Additionally, Pappas does not teach that a bush (5) that comprises a smooth surface as if claimed. The Examiner argues that this claim element is present in Pappas by inherency. Specifically, she asserts that the bushing's (340)[1] "articulation with the tibial body 501 requires that the bushing surface is smooth. Such reason cannot be held to meet the standard of a cogent technical reason, as is required to meet the burden of establishing the presence of a claim element by inherency. See, MPEP 2112 ("In relying upon the theory of inherency, the Examine must provide a basis in fact and/or a technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ 2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (The Board reversed the Examiner's finding of inherency on the basis that the Examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.)

In contrast, the bush (5) as recited in the claims has a smooth surface. Such surface facilitates the atrophy of the tissues surround the bush in situ and permits development of a seal.

For at least these reasons, it is submitted that the claims 1, 6, and 14 are not anticipated by the teachings of Pappas.

Claims 2, 3, 5, and 11: The Examiner applies Pappas as described above but acknowledges that Pappas does not expressly teach the claimed length ratio of the widening bush or an antibacterial/titanium bush or adaptation tube. The Examiner contends that the ratio could be determined through routine experimentation and relies on Pappas for a teaching that preferred metal materials may include titanium alloy with a ceramic titanium nitride coating. Further, without providing support for this conclusion, the Examiner contends that titanium can be interpreted as an antibacterial effect because it is a "well known body-compatible material and does not encourage the growth of bacteria."

The proposed modified version of Pappas does not teach or suggest all elements of the invention. First, for the reasons given above and incorporated herein by reference, Pappas lacks any teaching or suggestion of at least two elements that are present in the claims. The Examiner has provided no proposal for a modified version of Pappas that remedies these at least two deficiencies.

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[1] As noted above, the bushing 340 is not a structural element that corresponds to the bush (5) of the claims; the applicants accept that the surface of 340 is under discussion sole for the purpose of rebutting the Examiner's initial argument.

Even if such elements were present, and they are not, a person of skill in the art would not have had any reason to make the modification proposed. First, there was no reason that would have caused a person of skill in the art to "optimize" the bushing 340 of Pappas to arrive at the invention as claimed. Bushing 340, as explained above, does not correspond to the bush (5) as recited in the claim. Significantly, bushing 340 does not make contact with any surrounding body tissue when in situ. The length:length ratio helps to aid in the formation of the seal (by atrophy of the surrounding tissues); since the bushing 340 does not (and cannot, by virtue of the fact it is enclosed in another structure) play this role in the Pappas implant, a person of skill would have had no reason to make the modification.

Nor would a person of skill have had any reason to modify Pappas to include an antibacterial, titanium or other "body-compatible" material as the Examiner suggests. Bushing 340 makes no contact with living tissue as it is enclosed in the tibial body structure. Thus, there is no reason a person of skill in the art would have decided to decrease the bacterial population and/or increase the "body-compatibility" of a component that does not contact tissue.

Claims 4, 7 and 8:

The Examiner applies Pappas as in the anticipation rejection. However, Pappas, as acknowledged by the Examiner, does not teach that the bush or adaptation tube is made with silver. To remedy this deficiency the Examiner applies Scales. According to the Examiner Scales teaches that silver is a known material used for surgical implants for the purpose of providing a localized antimicrobial effect. According to the Examiner, the surgical implants taught by Scales would "necessarily include" the mounting, bush, and adaptation tube of the current invention.

The proposed combination of Pappas and Scales does not teach or suggest all elements of the invention. For the reasons given above and incorporated herein by reference, Pappas lacks any teaching or suggestion of at least two elements that are present in the claims. Scales as applied by the Examiner does not include any disclosures that remedy these at least two deficiencies.

Even if such elements were present, and they are not, a person of skill in the art would not have had any reason to make the modification proposed. A person of skill in the art would have had no reason to modify Pappas to include a silver bushing 340. Bushing 340 makes no

contact with living tissue as it is enclosed in the tibial body structure. Thus, there is no reason a person of skill in the art would have considered it important or desirable to decrease the bacterial population and/or increase the "body-compatibility" of a component that does not contact tissue.

Claims 9 and 10

The Examiner applies Pappas as in the anticipation rejection. However, the Examiner acknowledges that Pappas does not teach the use of hydroxyapatite or calcium phosphate. Blunn, according to the Examiner, teaches that hydroxyapatite or calcium phosphate is a known material used for the purpose of encouraging osseous integration.

The combination of Pappas and Blunn does not teach or suggest all elements of the invention. For the reasons given above and incorporated herein by reference, Pappas lacks any teaching or suggestion of at least two elements that are present in the claims. Blunn as applied by the Examiner does not include any disclosures that remedy these at least two deficiencies.

In addition, a person of skill in the art would not have been motivated to make the combination proposed by the Examiner. Blunn describes a prosthesis for a missing digit, tooth or limb that is implanted into the bone and becomes part of the bone's structure. Pappas is a knee joint. A person of skill would not have made the combination proposed.

Claim 12

The Examiner applies Pappas as above in the anticipation rejection. The Examiner acknowledges that Pappas does not teach a plasma titanium spray coating for the adaptation tube. However, according to the Examiner, Marshall teaches that plasma titanium spray is a known material that can be used for the purpose of contributing to long-term bone or tissue in growth.

The combination of Pappas and Marshall does not teach or suggest all elements of the invention. For the reasons given above and incorporated herein by reference, Pappas lacks any teaching or suggestion of at least two elements that are present in the claims. Marshall as applied by the Examiner does not include any disclosures that remedy these at least two deficiencies.

Nor would a person of skill in the art have had a reason to make the combination of Pappas and Marshall. Marshall teaches use fop spray coated femoral components in hip

prostheses. Pappas is a knee joint. A person of skill would not have made the combination proposed.

Claim 13

The Examiner applies Pappas as with respect to the anticipation rejection. The Examiner does concede that Pappas does not teach the use of polyurethane for the construction of the adaption tube. Spaans is applied to remedy the deficiency. Spaans allegedly teaches that polyurethane is a biomedical material that is used to process implants for the purpose of "having good mechanical properties".

The combination of Pappas and Spaans does not teach or suggest all elements of the invention. For the reasons given above and incorporated herein by reference, Pappas lacks any teaching or suggestion of at least two elements that are present in the claims. Spaans as applied by the Examiner does not include any disclosures that remedy these at least two deficiencies.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the applicant has distinguished over all of the cited prior art. Reconsideration and allowance of the claims at the earliest opportunity is respectfully solicited.

Respectfully submitted,

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(Date)

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